

REMARKS

Claims 1-43 are pending in the present application.

The Examiner has required election in the present application between:

Group I, claims 1 and 2, drawn to a peptide which is a part of the epitope in human IL-15 responsible for high-affinity binding to the receptor, and has the sequence of the region of hIL-15;

Group II, claim 3, drawn to a nucleic acid coding for the peptide; and

Group III, claims 4-15, 27-30 and 37, drawn to an IL-15 mutein, a fragment thereof, and a drug thereof, wherein the mutein or the fragment is an IL-15 agonist; and

Group IV, claims 4-7, 16-28, 31-33 and 39, drawn to an IL-15 mutein, and a fragment thereof, wherein the mutein or the fragment is an IL-15 antagonist; and

Group V, claims 34-36 in part, drawn to a nucleic acid coding for the mutein or a fragment thereof, a vector containing the nucleic acid and a host cell thereof, wherein the mutein or the fragment is an IL-15 agonist; and

Group VI, claims 34-36 in part, drawn to a nucleic acid coding for the mutein or a fragment thereof, a vector containing the nucleic acid and a host cell thereof, wherein the mutein or the fragment is an IL-15 antagonist; and

Group VII, claim 38, drawn to use of an IL-15 mutein or a fragment thereof for the manufacture of an anti-cancer or anti-immunodeficiency drug, wherein the mutein or the fragment is an IL-15 agonist;

Group VIII, claim 40, drawn to use of an IL-15 mutein or a fragment thereof for the manufacture of an anti-immunodeficiency drug, wherein the mutein or the fragment is an IL-15 antagonist; and

Group IX, claims 41-43, drawn to a process for screening for an IL-15 agonist or antagonist.

For the purpose of examination of the present application, Applicants elect, with traverse, Group III, Claims 4-15, 27-30 and 37.

The Examiner identified the following groups as allegedly not meeting with the requirement of unity of invention pursuant to Rule 13.1 PCT:

Group	Claims	Subject-matter
I	1-2	Epitopic peptides
II	3	Nucleic acids coding for said epitopic peptides
III	4-15 and 27-30, 37	Agonistic muteins
IV	4-7, 16-28 and 31-33, 39	Antagonistic muteins
V	34-36, in part	Nucleic acids coding for said agonistic muteins
VI	34-36, in part	Nucleic acids coding for said antagonistic muteins
VII	38	Use of said agonistic mutein in the manufacture of an anti-cancer or anti-immunodeficiency drug
VIII	40	Use of said antagonistic mutein in the manufacture of an immunodeficiency drug
IX	41-43	Process for screening for an IL-15 agonist or antagonist

The Restriction Requirement is based on the argument that:

- a. claim 1 would not be novel in view of Grabstein et al.;
- b. as neither the peptide of claim 1 nor the nucleic acid coding this peptide would be novel, the technical feature of the polypeptide sequence would not be special, whereby groups I and II would not be linked by a single inventive concept under Rule 13.1 PCT;
- c. the products in groups III-IV would be physically and/or functionally distinct chemical entities, and would therefore not be linked by a single inventive concept under Rule 13.1 PCT; and
- d. the additional methods of groups VII-IX would not correspond to the main invention and would therefore not be linked by a single inventive concept under Rule 13.1 PCT.

Applicants respectfully traverse this argument.

Rule 13.1 PCT reads:

"The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention")." [emphasis added].

The terms "*general*" and "*concept*" that are recited in Rule 13.1 PCT makes it clear that the essence of the invention should be duly taken into account. It seems that it has been overlooked in said Office action.

Indeed, the present application is the first description of the epitopes of IL-15. These epitopes are novel and inventive. At least for that reason, unity of invention should have been acknowledged.

The inventors have further produced muteins, which derive from the identification of said epitopes by mutation(s). These muteins are claimed in Groups III and IV. The claimed muteins derive from said epitopes by mutation(s), and share at least this corresponding special technical feature(s) in the sense of Rule 13.1 PCT. The subject-matter of the claims all share corresponding technical feature(s), which are based on the identification of said IL-15 epitopes.

It is furthermore submitted that the Examiner's argumentation mentioned in paragraphs c. and d. above is not understood by Applicants.

More particularly, it is not understood how the alleged fact that products would be physically and/or functionally distinct chemical entities would provide any legal basis to an objection on the ground of lack of unity of invention in the sense of Rule 13.1 PCT, and it is also not understood how the alleged assumption that a certain subject-matter would not correspond to the main Invention would provide any legal basis to an objection on the ground of lack of unity of invention in the sense of Rule 13.1 PCT.

Applicants further submit the following argumentation.

Claims 4-7 are common to both groups III and IV.

These claims are novel and inventive.

If the reasoning of the current Office Action were to be followed, it should then be recognized that groups III and IV are linked by a single inventive concept under Rule 13.1 PCT. Groups V and VI relate to the nucleic acids coding for the muteins of Group III-IV, and therefore share a corresponding special technical feature in the sense of Rule 13.1 PCT. Groups VII, VIII and IX relate to some applications that can be made of the muteins of the invention. Therefore, the subject-matter of groups VII, VIII and IX share a special technical feature in the sense of Rule 13.1 PCT with Group III-IV.

As a consequence, unity of invention of Groups III to IX should be acknowledged.
Withdrawal of the Restriction Requirement is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Registration No 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

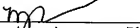
☒ Attached is a Petition for Extension of Time.

☒ Attached hereto is the fee transmittal listing the required fees.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 
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